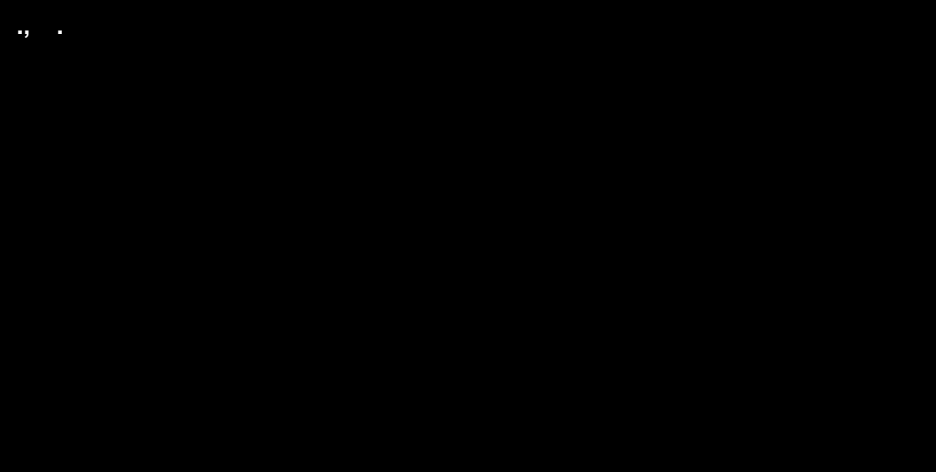


**SUPPORTING DOCUMENTS:**



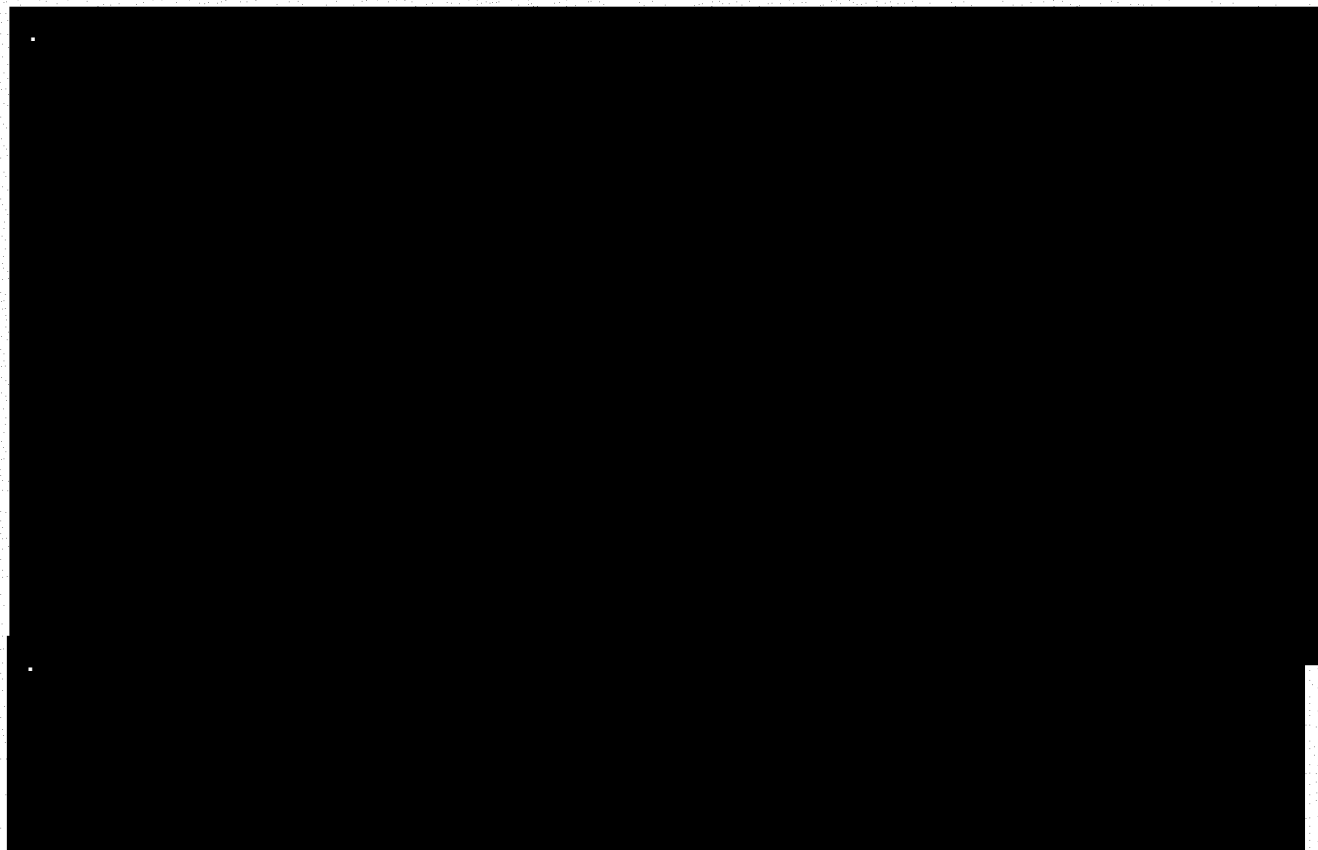
**RELATED DOCUMENTS (if applicable):** *Amendments* dated 6-16-98; 7-06-98; 7-21-98; 8-06-98; 8-27-98; 9-28-98; and 11-10-98.



**CONSULTS:** Microbiology Consult - see Micro. Review # 1

**REMARKS:** NDA 20-924 provides information regarding Cernevit™-12 IV Multivitamins for Infusion, which is a lyophilized sterile powder containing both water-soluble and fat-soluble vitamins combined with a mixed micelle excipient packaged in an amber glass vial for reconstitution. This drug product is intended for use a part of a Total Parenteral Nutrition (TPN) package, and should be further diluted for use in the TPN package.





cc:  
Org. NDA 20-924  
HFD-510  
HFD-820/Chemist/D Lewis/DGWu  
HFD-510/S. McCort/CSO  
HFD-102/

R/D Init by: /S/

Filename: NDA 20-924, Review

3/2/99

/S/

David B. Lewis, Ph.D.  
Review Chemist

APPEARS THIS WAY ON ORIGINAL